CHAPTER 2

Data Review Reports

2-1. Introduction.

A data review report documents the PB data evaluation. At least one data review report must be generated for each data sample delivery group. The data review report may address the data packages for several analytical methods. The format of the document is not as important as its content. However, a uniform format is recommended to facilitate data evaluation activities. The elements presented below must be included in a data review report.

2-2. Cover Page.

The cover page specifies the following information:

a. Unique report ID number.

b. Name and address of data reviewer.

c. Contract number.

d. Client name and address.

e. Project name and site location.

f. Statement of data authenticity and official signature of release.

2-3. Cover Letter.

a. Project name (or brief description of the project).

b. Site name (location from which the samples were collected).

c. Parties responsible for evaluating the data and the date the evaluation was performed (including a point of contact for questions with phone and facsimile numbers).

d. Technical criteria used to evaluate the data (e.g., cited as a reference).

e. Laboratory that performed the analyses (name, location, and point of contact).

f. Description of the samples that were evaluated, including the following:

(1) Number of samples.

(2) Matrix.

(3) Environmental samples associated with the field QC samples.

(4) Field and laboratory ID numbers.

(5) Date samples were collected in the field.

(6) Preparatory and determinative methods of analysis (including method numbers).

(7) Target analytes or parameters.

(8) Date the laboratory analyses were performed.

(9) Date the data package from the laboratory was received.

2-4. Executive Summary.

a. The objective of the *Executive Summary* is to *concisely* describe the overall quality of the data package in a manner that is comprehensible to an individual *lacking an extensive background in analytical chemistry*. Major areas of concerns and any information which would aid the reader to better understand the quality or usability of the data must be discussed in general terms. For example, Executive Summary may state that a complete review of the data could not be performed because of missing information or it may state that no significant QC problems were observed.

b. When *major* QC problems are observed after the data review process, when possible, the Executive Summary must indicate whether these problems primarily resulted from unacceptable laboratory performance, **matrix interference**, or problems associated with the sample collection activities. If the QC problems resulted because the laboratory or field personnel failed to follow the requirements in the Work Plan or QAPP, this information should be highlighted. The Executive Summary should also recommend corrective actions to improve the quality of the data. The format and content of the Executive Summary are otherwise left to the discretion of the author.

2-5. Technical Summary.

a. The *Technical Summary* must discuss the quality of the data package in terms of specific QC elements and must be divided into subsections—one for each QC element in which problems were identified (e.g., “Holding Times,” “Laboratory Control Samples,” “Matrix Spikes,” and “Continuing Calibration Verifications”). The Technical Summary must discuss the effects of QC problems in the context of sensitivity (e.g., false negatives due to high detection limits), precision (e.g., high variability), accuracy (e.g., high or low bias), representativeness (e.g., blank contamination), completeness (e.g., missing information), and comparability (e.g., failure to use specified methodology).

b. The Technical Summary explain *why* each result was qualified (e.g., matrix interference and blank contamination). This is especially critical when project DQOs are not well defined for a particular parameter or when qualification is based upon a high degree of professional judgment (e.g., due to the complexity of the project's objectives or the environmental population being sampled). Any changes made to the laboratory's reported data (e.g., due to misidentification, transcription errors, or calculation errors) must be identified and the samples affected by each QC problem should be listed in a tabular format.

c. The Technical Summary must identify QC problems as having a *major* or *minor* impact on data quality or usability. The Technical Summary should also distinguish systematic errors from random errors. Systematic errors resulting from blunders (e.g., transcription errors) should also be distinguished form systematic effects that bias the results (e.g., from poor extraction efficiency). When possible, the Technical Summary should identify the *direction of bias (high or low).* In addition, problems giving rise to *qualitative* uncertainties must be distinguished from those giving rise to *quantitative* uncertainties. *Qualitative* uncertainty refers to uncertainty associated with the *identification* of an analyte in an environmental sample. *Quantitative* uncertainty refers to error associated with the determination of the amount of an identified analyte. (Refer to the definitions of the N and J qualifiers in Chapter 3.)

d. When possible, field sampling uncertainty must be distinguished from laboratory analytical uncertainty. Problems arising from missing data and QC failures resulting from substandard laboratory performance (e.g., out-of-control LCS recoveries) and substandard sample collection procedures (e.g., the lack of sample preservation) must be highlighted. When major QC problems are observed, corrective actions should be recommended. However, it should be noted that the major of objective of the evaluation is to determine the potential usability of the data and not contractual compliance (e.g., contractually noncompliant data may or may not be usable.)

e. The reviewer should *avoid* statements pertaining to the *ultimate* usability of the data. As defined in this document, PB data review results in "usability screening" rather than a full usability assessment. In particular, unless there is a high degree of confidence that a set of results must be rejected (e.g., the results are being qualified with the R flag), adjectives such as "unusable" and "unacceptable" should be avoided (e.g., the results should be described as "tentatively unusable.") The use of these terms in data review reports may be interpreted as contradictory by regulators in situations where the end users determine that the data are useful for project purposes in spite of the QC problems. Similarly, terms such as "usable," "acceptable," and "valid," should only be used when the report *explicitly* defines these terms to mean that the data are *potentially* usable or that the data review specifications have been satisfied. Examples of preferred terminology are presented below.

(1) "The results for the aqueous HVOCs (laboratory batch 50603, samples SL5-3031-1 to SL-3031-6) may possess a negative bias because the samples were analyzed one day beyond the **holding time limit**; detections are qualified with the J- flag (i.e., as estimated with suspected low bias) and **nondetections** are qualified with the UN flag to indicate the possibility of false negatives ...".

(2) "The **Chain-Of-Custody** was not signed in the field. This may adversely impact the legal defensibility of the data. However, no results were qualified based upon this observation ..."

(3) "The low LCS **recovery** (11%) for the semivolatile pentachlorophenol for (laboratory) Batch 49382 is indicative of a large negative bias for the associated samples (GW-2-21-972, GW-2-21-972-FD, GW-2-21-972-MS, and GW-2-21-973 to GW-2-21-980). Detected concentrations of the analyte are considered to be minimum values and nondetections are considered to be unreliable at the stated reporting limits. Reported concentrations (nondetections and detections) of the analyte below the project-specified action level are qualified with the X flag as tentatively unusable because they do not demonstrate that the analyte is present below the action level. Detections above the action level are qualified with the J- flag ..."

2-6. Data Summary Tables.

Present qualified results for the environmental samples in a tabular format and list the definitions of all data qualifiers. Use footnotes to briefly explain why the data were qualified. The summary tables should also list the detection and quantitation limits and any project-specific action levels or requirements for sensitivity. (It is recommended that this be done in a format that will enable the data to be readily exported to the project report.) The header information for each table typically includes the following information:

a. Project name and location.

b. Laboratory name and location (City and State).

c. Field and laboratory ID numbers.

d. Matrix type.

e. Preparatory and determinative method.

f. Date of sampling, analysis, and preparation.

g. Amount of sample processed and analyzed (including extract volume).

h. Dilution factors.

i. Percent moisture (for solid samples).

j. Concentration units.

2-7. Project Specific Communications.

This section contains pertinent communications (e.g., phone logs, E-mail, and letters) between the data reviewer and any agencies or parties that possess an interest in the quality of the data

(e.g., the analytical laboratory, the contractor that collected the samples, the USACE district field office, and regulators). Examples are listed below:

a. Requests to the analytical laboratory for the submittal of additional information.

b. Communications with the client concerning major data quality deficiencies.

c. Communications with the samplers to address QC problems associated with sample collection.

d. Inquiries from regulatory authorities.

e. Requests from the client for quick turnaround time.

f. Amendments of the data quality objectives from the client.

2-8. Project Specific Communications.

a. Include checklists that were used to review the data packages in an appendix of the data review report. Checklists demonstrate that the data packages were assessed for overall completeness prior to the technical evaluation and appropriate QC elements were assessed during the technical evaluation (e.g., holding times, initial calibration, and laboratory control samples).

b. Include worksheets that were used to verify the laboratory's reported results (e.g., any recalculations that were performed). When errors are observed, photocopies of the laboratory's original data and any relevant field documents should be used to *illustrate* the corrections performed. For example, if incorrect concentration units were reported for all the samples, it would only be necessary to illustrate the correction for one sample. Note that, depending upon the severity of the errors and the contractual requirements for the analyses, the laboratory may be required to correct the results and resubmit the data packages.